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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,555	06/04/2001	Michael Joseph Luzzio	PC10795A	7601

7590 04/18/2003  
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EXAMINER

LIU, HONG

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/873,555

Applicant(s)

LUZZIO ET AL.

Examiner

Hong Liu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26, 29-49 and 59-68 is/are pending in the application.
- 4a) Of the above claim(s) 59-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 29-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-26, 29-49, and 59-68 are pending in this application.

This action is in response to the applicants' amendment and reply filed on March 28, 2003.

### **Response to Arguments**

Applicants' arguments filed on March 28, 2003 have been fully considered but they are not persuasive. Rejections under 35 U.S.C. 112, 103(a) are maintained.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

The amended claims are object to as they still contain the non-elected subject matter that was withdrawn from consideration in the previous office action. Applicants are expected to cancel the non-elected subject matter.

### ***Claim Rejections - 35 USC § 112***

Claims 1-12, 15-26, and 49 remain rejected under 35 U.S.C. 112, first paragraph, for reasons already made of record notwithstanding applicants' traverse. The Examiner in this case has provided both "evidence" and "reasoning" to cast doubt on the sufficiency of enablement provided in the instant closure. See rejection made in the previous office and those maintained below.

The claims are still not commensurate in scope as to the diversity of Markush groups, aromatic groups, heteroaromatic and heterocyclic groups of R2. The instant case is similar to In

re Lund, 153 USPQ 625, in which the Court agreed the specific aldehyde reactants mentioned in the specification fell within a limited range and thus far short of the claims' scope. Applicants urge that the compounds embraced herein are active as anti-hyperproliferative agents, and thus all of the functional moieties and heterocyclic/aromatic groups which are embraced by these claims have the anti-hyperproliferative activity. However, no reason or evidence has been provided to support applicants' position. As was previously mentioned, no compounds of the instant invention where R2 is other than indole or quinoline are seen to have been tested for their anti-hyperproliferative activity. Thus, applicants have not provided adequate information that the instant compounds as an entire class have the required activities needed to practice the invention, and therefore, there is no reasonable basis for assuming that the variety of substituents embraced by the claims will all share the same physiological properties. See MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Note also the quote taken from Surrey, previously cited, "Manifestly, a disclosure which does not adequately establish compounds as useful for an asserted purpose does not adequately describe "how to use" these compounds either." Also note the quote taken from In re Cavallito 127 USPQ 202 which was cited in Surrey, previously cited, at page 730; "...where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful...An applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others." Note Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use

Markush members embraced thereby in full, clear and exact terms. See *In re Fouche*, 169 USPQ 429. Furthermore, applicants rely on the working examples listed in the variety of Tables in the specification, but as mentioned before, these examples are limited to a homogenous group of compounds. The specification is silent as to the availability of the necessary starting materials needed for preparing the compounds wherein R2 is other than indole or quinoline. Note *In re Armbruster*, 185 USPQ 152, wherein it was stated that a specification which "describes the invention as broadly as it is claimed...does not necessarily also "enable" one skilled in the art to make or use the claimed invention."

The word "prodrug" is rejected under 35 U.S.C. 112, first paragraph for reasons already made of record and notwithstanding applicants' traverse. Applicants argue that the specification provides definition for "prodrug" on pages 17 and 18. No such definition could be found on these pages. Therefore, the term is still too broad to enable one skilled in the art to determine how the prodrug is converted to active compounds, by what mechanisms and at what site the prodrug will be activated, what *in vivo* enzymes are likely involved in cleaving the protected group, etc. All these factors are uncertain and require one skilled in the art to spend undue amount of time to practice the invention. For these reasons, the rejection is maintained.

The rejection to claims 1-4, 15-18, 30-32, and 40-42 under 35 U.S.C. 112, second paragraph, is maintained for reasons already made of record in the previous office action. For the word "heterocyclic," applicants argue that these terms are defined in the specification and thus definite in light of the specification. However, reading a claim in light of the specification is quite different from reading limitations of the specification into the claim. See *In re Prater*, 415

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F.2nd 1393, 162 USPQ 541. These claims themselves do not carry the limitation as specified in the specification. When the claims having these phrases are given the broadest interpretation, they are still open-ended in terms of the array of heteroatoms, size of the rings, as well as nature of atoms as ring members.

The rejection to claims 27 and 28 are hereby withdrawn in view of the cancellation of these claims. The rejection to claim 49 is also withdrawn, as applicants' arguments are found persuasive.

### ***Claim Rejections - 35 USC § 103***

The rejection to claims 1-26 and 29-49 under 35 U.S.C. 103(a) as being unpatentable over Munchhof et al. (WO 99/24440) is maintained. Applicant's arguments have been fully considered but they are not persuasive. Applicants' argue that the definition of R11 in the reference and the application is completely different and therefore, the reference cannot encompass applicants' claimed invention. Applicants listed the definition of R11 of the present application, which include -C(O)NR12R13 (see page 16 of the Response). Applicants then stated that "in contrast," the definition of R11 of the reference is -C(O)NR6R9... (see page 17 of the Response). Both R12 and R13 are defined as hydrogen and alkyl. So are R6 and R7. Since the Examiner could not see any "contrast" between at least these two groups, applicants' claims were still deemed to be encompassed by the reference and the rejection is thus maintained.

### ***Conclusion***


1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Examiner Hong Liu whose telephone number is (703) 306-5814. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at (703) 308-4716. The fax phone number for this group is (703) 308-4734 for "unofficial" purposes and the actual number for official business is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose number is (703) 308-1235.

h. liu  
April 17, 2003

  
Mukund Shah  
Supervisory Patent Examiner  
Art Unit 1624